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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,410	12/12/2000	Burkhard Goke	0206-UTL-9	8826

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ARNOLD & PORTER
Attn: IP Docketing Departement, Room 1126B
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Washington, DC 20004-1206

EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,410	GOKE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO NON-COMPLIANT AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and response to non-compliant amendment filed 10/20/04 and the remarks filed 1/27/04 are acknowledged, entered and considered. In view of Applicant's request claims 1-9 have been canceled, claims 10, 13, 14, 17, 18, 24, 27, 28, 31, 32 and 35-40 have been amended and claims 41-58 have been added. Thus, claims 10-58 are now pending in the application. The objection to the specification and claims and the rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 103(a) and 35 U.S.C. 102(b) for composition claims (i.e. canceled claims 1-9) are withdrawn in view of Applicant's amendment and remarks filed 10/20/04 and 1/27,04, respectively. However, the rejection under 35 U.S.C. 102(b) for claims 39, 40 and newly submitted claims 42, and 43 are maintained for the reasons of record.

CLAIM REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 40 and newly submitted claims 42 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/08531.

Applicant's arguments filed 1/27/04 have been fully considered but they are not persuasive. Applicant's arguments that the reference WO 98/08531 does not disclose methods for reducing the risk of cardiovascular or cerebrovascular events as set forth in amended claims 39 and 40 is unpersuasive. Contrary to Applicant's arguments the reference WO 98/08531 clearly discloses a method and a composition comprising a compound from the group consisting of GLP-1, GLP-1 analogs, GLP-1 derivatives, and pharmaceutically acceptable salts thereof, at a dose effective to normalize blood glucose by increasing the glucose level in a patient with impaired glucose tolerance (IGT). Thus, the reference as shown in the abstract, Examples 1 and 2 and claims 1-13, clearly teaches a method of reducing mortality and morbidity after myocardial infraction by administering GLP-1 and a GLP-1 analog or derivative thereof at a dose effective to normalize blood glucose since normalizing blood glucose will reduce the risk of cardiovascular or cerebrovascular events (for support, See page 1, lines 18-21 in the instant specification which states that subjects with IGT are at high risk for the development of cardiovascular or NIDDM or type 2 diabetes, and as such, the reference discloses the use of GLP-1 or analogs in treatment of myocardial infarction which meets the limitations of claims 39 and 40. Thus, in the absence of evidence to the contrary, the claimed method of treating individual whose symptoms indicate increased risk of a cardiovascular or cerebrovascular events by administering the claimed composition thereof by the reference anticipates claims 39, 40, 42 and 43 as drafted.

NEW GROUND OF REJECTION

The following is a new ground of rejection necessitated by Applicant's amendment.

CLAIMS REJECTION-35 U.S.C. § 112 1st PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-38, 41 and 44-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 10, 36-40 and 44 as amended on 10/20/04 contain new matter because the original specification does not appear to support **who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM)**. Independent claims 10, 36-40 and 44 have no support for **who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM)** from the original disclosure because there is no disclosure in the specification as now claimed. Although, Applicant alleges on page 15, second paragraph of the remarks filed 1/27/04 that support for amended and new claims drawn to treating individuals with impaired glucose tolerance (IGT) who have not been diagnosed with NIDDM ca be found in the specification in general, and in particular at least at page 3, lines 3-10, where the specification states the need for a

therapy to treat IGT, while acknowledging that studies exist for the application of GLP-1 in case of NIDDM. However, the above citation or anywhere in the instant specification have no support for the treatment of IGT in a patient **who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM)**. Thus, Applicant respectfully requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure.

CLAIMS REJECTION-35 U.S.C. 112, 1st PARAGRAPH

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant specification for the claimed method of treating an individual with impaired tolerance who has been diagnosed with non-insulin dependent diabetes mellitus (NIDDM) by administering a **composition comprising an exendin or a variant of said exendin, wherein the exendin is exendin-3 or exendin-4** as claimed in independent claim 44 and dependent claims 45 and 46 and the additional limitations contained in dependent

claims 47-54. Also, there is no support for a method of reducing a risk of a cardiovascular or cerebrovascular events by administering to an individual a **composition comprising an exendin or a variant thereof** in the manner claimed in claims 55-58. It is noted as stated by Applicant on page 16, second paragraph of the remarks filed 1/27/04 that added claims 44-58 find support *inter alia* at Table 1 on page 10, to page 11, lines 11; and page 13; lines 22-23 of the specification. However, none of the cited Table and pages above in the instant specification support methods involving exendin and variants thereof (i.e., administering to an individual exendin and variants thereof) to treat individuals with IGT or methods for reducing a risk of a cardiovascular or cerebrovascular events in the manner claimed in claims 44-58. Table 1 discloses 6 naturally occurring peptides (a, b, d, e, f and g) which are homologous in positions 1, 7, 11 and 18. GLP-1 and exendins 3 and 4 (a, b and d) are further homologous in positions 4, 5, 6, 8, 9, 15, 22, 23, 25, 26 and 29. Further, the instant specification states that of the 30 residues of GLP-1, exendins 3 and 4 are identical in 15 positions and equivalent in 5 additional positions. The only positions where radical changes are evident are at residues 16, 17, 19, 21,27, 28 and 30. Exendins also have 9 extra residues at the carboxyl terminus. Thus, in view of exendins radical structural changes and in view of having 9 extra residues at the carboxyl terminus, the scope of the currently presented claims 44-58 is not supported in the instant specification.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

AAM Mohamed/AAM
December 22, 2004